Dräger medical
A Dräger and Siemens Company

k073113

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.87, 21 CFR 807.92, Format for Traditional and Abbreviated 510(k) s.

1. **Name of Submitter, Contact Person and Date Summary Prepared:**

JAN - 3 2008

Name: Draeger Medical Systems, Inc.

Address: 6 Tech Dr Andover MA 01810

Phone: 978.379.8124
Fax: 978.379.8330

Official Contact: Genci Omari,
Regulatory Affairs Manager

Date of Preparation: 18 October 2007

2. **Device Trade Name and Common Name:**

Trade Name: Infinity PICCO Pod

Common/Usual Name: Single-function, preprogrammed diagnostic computer

Classification: 21 CFR 870.1435

3. **Product Code:** DXG

Device Class: Class II

4. **Legally Marketed Equivalent Device Names:**

Substantial equivalence is claimed to the Pulsion PICCO Plus System 510(k) k060898

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5. **Performance Standards:** None

6. **Description of the Device:** The Infinity PICCO Pod is an optional accessory to Draeger Medical Systems' Infinity patient monitoring series (Delta, Delta XL, and Kappa) that provides for determination and monitoring of cardiopulmonary and circulatory variables.

   The Infinity PICCO Pod acquires cardiac output thermal and invasive blood pressure data from Pulsion Medical transducers and sends this data to the Draeger patient monitors. The Draeger patient monitors contain Pulsion algorithms which are run on this data to calculate a number of cardiopulmonary and circulatory variables.

7. **Intended Use of the Device:**
   The Infinity PICCO Pod is intended for determination and monitoring of cardiopulmonary and circulatory variables. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PICCO Pod measures systolic, and diastolic and derives mean arterial pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PiCCO Plus presents the derived parameters indexed to body surface area.

8. **Comparison of technological characteristics with Predicate Devices:**
   The Draeger Infinity PICCO Pod uses the same algorithms as its predicate, the Pulsion PiCCO Plus. The Pulsion PiCCO plus integrates all functionality into one device, where the Infinity PICCO Pod is a separate pod for signal acquisition from the patient, the data from the pod is sent to the Draeger patient monitor for algorithm processing and display.

9. **Discussion of Non-clinical Studies:**
   Extensive bench testing has been performed to insure that the hardware of the Infinity PICCO Pod is equivalent to the hardware of the Pulsion PiCCO Plus.

   Extensive bench testing has been performed to insure that the software as implemented in the Infinity PICCO Pod is equivalent to that of the Pulsion PiCCO Plus.

   Extensive simulator based testing has been performed to insure that the Infinity PICCO Pod as a complete device is equivalent to that of the Pulsion PiCCO Plus as a complete device.

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10. **Conclusion:**
The Infinity PICCO Pod is as safe and effective as its predicate, the Pulsion PiCCO Plus, and it provides a convenient means to continuously monitor a variety of circulatory parameters.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2008

Dräger Medical Systems, Inc.
c/o Mr. Genci Omari
Regulatory Affairs Manager
6 Tech Drive
Andover, MA 01810

Re: K073113
Infinity PiCCO Pod, Model MS16734
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function Preprogrammed Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DXG
Dated: October 18, 2007
Received: November 5, 2007

Dear Mr. Omari:

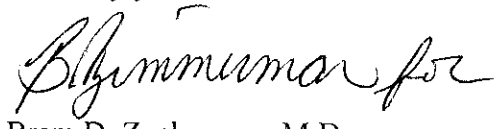
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K073113

Device Name: Infinity PICCO Pod

Indications for Use:

The Draeger Infinity PICCO Pod is intended for determination and monitoring of cardiopulmonary and circulatory variables. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the Infinity PICCO Pod measures systolic, diastolic and derives mean arterial pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the monitor to which, the PICCO Pod is connected, presents the derived parameters indexed to body surface area.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073113

COMPANY CONFIDENTIAL

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